

REC'D 26 APR 2004

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 20 AUG 2004

WIPO

PCT

Applicant's or agent's file reference T3087 (C)	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/01465	International filing date (day/month/year) 13.02.2003	Priority date (day/month/year) 28.02.2002
International Patent Classification (IPC) or both national classification and IPC C12N15/82		
Applicant UNILEVER PLC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
  
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.
  
3. This report contains indications relating to the following items:
  - I  Basis of the opinion
  - II  Priority
  - III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV  Lack of unity of invention
  - V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI  Certain documents cited
  - VII  Certain defects in the international application
  - VIII  Certain observations on the international application

Date of submission of the demand 26.09.2003	Date of completion of this report 23.04.2004
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Oderwald, H Telephone No. +31 70 340-4274



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/01465

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-45 as originally filed

**Claims, Numbers**

1-21 as originally filed

**Drawings, Sheets**

1/11-11/11 as originally filed

**Sequence listing part of the description, pages:**

1-20, filed with the letter of 30.04.2003,

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description,      pages:
- the claims,      Nos.:
- the drawings,      sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/01465

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP03/01465

**Re Item V**

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: WO 00 44909 A (DU PONT ;JUNG WOOSUK (US); FADER GARY M (US); MCGONIGLE BRIAN (US)) 3 August 2000 (2000-08-03)
- D2: WO 00 53771 A (DIXON RICHARD A ;SAMUEL ROBERTS NOBLE FOUNDATIO (US); STEELE CHRIS) 14 September 2000 (2000-09-14) cited in the application
- D3: WO 99 47118 A (PROCTER & GAMBLE (US)) 23 September 1999 (1999-09-23)
- D4: WO 99 14351 A (DU PONT ;FADER GARY MICHAEL (US)) 25 March 1999 (1999-03-25)

**NOVELTY**

- i. The present application relates to the production of daidzein in transgenic plants. The production is achieved by the recombinant expression of the enzymes chalcone reductase (CHR) from Pisum, isoflavone synthase (IFS) from Glycine and chalcone isomerase (CHI) from Lotus.
- ii. D1 discloses genetically modified plants that produce daidzein (examples 13 and 14). The plants recombinantly expressed CHR and IFS. Both sequences were isolated from Glycine. The activation of CHI to further trigger the phenylpropanoid pathway has been disclosed. The document further describes plant extracts and uses thereof for the preparation of food and pharmaceuticals.
- iii. D2 discloses genetically modified plants that express IFS from Glycine. The identity of the disclosed nucleotide sequence with the IFS sequence of the present application (SEQ ID NO: 1, from Pisum) was 99,2%. Further disclosed was the production of daidzein by

recombinant expression of IFS in combination with CHR and CHI, extracts and uses thereof for the preparation of food and pharmaceuticals.

- iv. D3 discloses the use of flavonoids compounds (including daidzein) in cosmetics for the prevention or treatment of skin disorders.
- v. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1-21 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

#### **INVENTIVE STEP**

- vi. Even if claims 1-21 were rendered novel by e.g. restricting them (see e.g. point vii of the communication), no inventive step could be acknowledged for the following reason: It is generally known to the person skilled in the art that the feature "CHI from Lotus (SEQ ID NO: 5)" is an equivalent to the feature "CHI from Glycine" of document D4 and can be interchanged with that feature where circumstances make it desirable.

#### **CLARITY**

- vii. The terms "and/or derivatives thereof", "functional equivalents thereof" and "but not restricted to" used in claims 1, 3, 4, 6, 19-21 are vague and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).